

Exhibit 4



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May 17, 2023

Zydus Pharmaceuticals
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(Gandhinagar),
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Ahmedabad, Gujarat 382481

Zydus Pharmaceuticals USA Inc.
73 NJ-31,
Pennington, NJ 08534

Re: Zydus' Varenicline Tartrate

Dear Sir/Madam:

We write on behalf of Par Pharmaceuticals Inc. ("Par") to advise you that the U.S. Patent and Trademark Office ("PTO") has issued a patent to Par covering varenicline pharmaceutical compositions—U.S. Patent No. 11,602,537 ("537 patent"). A copy of the '537 patent is enclosed for your convenience. Par also has other patent applications pending before the PTO.

As issued, claims 1 and 2 of the '537 patent recite the following:

1. A pharmaceutical composition in the form of a tablet, comprising varenicline tartrate and means for controlling the level of N-nitroso-varenicline (7,8,9,10-tetrahydro-8-nitroso-6,10-Methano-6H-pyrazino [2,3-h][3] benzazepine) impurity to less than 50 ppm per tablet as measured by LC-ESI-HRMS (U.S. FDA Method), wherein the varenicline tartrate is dispersed in a maltodextrin matrix.
2. A pharmaceutical composition, comprising varenicline tartrate maltodextrin premix having less than 50 ppm N-nitroso-varenicline (7,8,9,10-tetrahydro-8-nitroso-6,10-Methano-6H-pyrazino [2,3-h][3] benzazepine) impurity as measured by LCMS.

Par believes that other varenicline tartrate products approved by the FDA are likely to infringe Par's issued patent and its other pending patent claims, including without limitation, the representative claims recited above. Par believes, for example, that in order to obtain a varenicline tartrate product with the low levels of nitrosamine impurity levels required by the FDA, the manufacturer will likely utilize the methods of making



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varenicline pharmaceutical products taught by the '537 patent. Par intends to enforce its patent rights as appropriate and warranted under the circumstances and therefore expects that it will seek to prevent other manufacturers of varenicline tartrate products from infringing upon those rights.

Par understands that you and/or your affiliates (collectively "Zydus") are developing varenicline tartrate products and/or have filed an ANDA seeking FDA approval to sell varenicline tartrate products. With that in mind, we write to give Zydus notice of Par's patent rights and an opportunity to take steps to avoid infringement. We trust that Zydus will respect Par's patent rights and will take any and all steps necessary to avoid infringing upon those rights.

Sincerely,

/s/ Robert Rhoad

Robert Rhoad

RDR

Enclosure